REMARKS

Status of Claims

Claims 1-13 and 20 are cancelled. Claims 14-19 and 21-24 are pending. Claims 14-16, 18, 19, 21, 22, and 24 have been amended. Claims 25-28 have been added.

Amendments to Claims

Claims 14-16, 18, 19, 21, 22, and 24 have been amended.

Support for the amendments to claims 14 and 19 can be found, *inter alia*, at paragraphs [0005], [0009], [0017], [0022] and [0023] of the specification as originally filed.

Support for the amendments to claims 18 and 24 can be found, *inter alia*, at paragraphs [0018], [0019], [0031] to [0035], and Figures 4A-4E of the specification as originally filed.

Claims 15, 16, 21, and 22 have been amended to be properly dependent from amended Claims 14 and 19. Support for the amendments to claims 15, 16, 21, and 22 can be found, *inter alia*, in the claims as originally filed.

Claims 25-28 have been added. Support for Claims 25-28 can be found, *inter alia*, at paragraphs [0018] and [0022] of the specification as originally filed.

No new matter has been added by way of these amendments. Entry of the amendments is respectfully requested.

Rejection Under 35 U.S.C. § 101

The Office has rejected claims 14-19 and 21-24 under 35 U.S.C. § 101 because the claimed invention is allegedly directed to non-statutory subject matter. Applicants respectfully traverse the rejection for the reasons presented below.

The Office states on page 4 of the OA that "there is no physical transformation because a process of designing a PKS gene, per se, i.e. without actually synthesizing the gene, does not

transform an article or physical subject to a different state or thing." Although Applicants do not necessarily agree with the position taken by the Office, in an effort to expedite prosecution, Applicants have amended independent claims 14 and 19 to include the phrase "using the alignment representing the structure of the PKS gene to produce the desired polyketide."

On page 5 of the OA, the Office states that the "last steps of the claims, e.g. claim 1, are amended to recite storing or displaying the alignment representing the structure of a new PKS gene; or repeating steps (b) and (c), i.e. the steps of 'comparing' and 'identifying,' meaning that, at least for one embodiment, the step of 'storing or displaying' is optional." Applicants respectfully disagree with this statement. Independent claims 1 and 19 all recite the phrase "or (B) the method of (A), wherein steps (b) and (c) are repeated." Thus, the method of (A) includes steps (a) to (f), which include the step of "storing or displaying the alignment" (step (e)).

The Office states on pages 5-8 of the OA that claim 18 is drawn to nonstatutory subject matter. Specifically, the Office states that "since the method process of claim 14, etc. does not produce a useful, concrete and tangible result …, the computer readable medium comprising a program for the method does not produce a useful, concrete and tangible result for the same reasons." Applicants have amended claim 18 to be dependent from amended claim 14; amended claim 14 is drawn to statutory subject matter.

Lastly, the Office states that claim 24 is also drawn to non-statutory subject matter for the reasons set forth on page 8 of the OA. Although Applicants do not necessarily agree with the position taken by the Office, in an effort to expedite prosecution, Applicants have removed the language of rejected claim 24.

For the reasons set forth above, Applicants respectfully request that the rejection of claims 14-19 and 21-24 under 35 U.S.C. § 101 be withdrawn.

Rejection Under 35 U.S.C. § 112, First Paragraph, Written Description.

Claims 14-19 and 21-24 are rejected under 35 U.S.C. § 112, first paragraph, allegedly failing to comply with the written description requirement.

As set forth on pages 8-9 of the OA, the Office states that in regards to claims 14, 18 and 19, that a "review of the specification reveals that it discloses neither that each alphanumeric symbol in the second string in a database represents a monomer unit of a known polyketide, nor that [] each alphanumeric symbol also represents a polyketide molecule of a PKS gene."

Regarding the phrase "wherein each alphanumeric symbol in the second string represents a monomer unit of the known polyketide and also represents a polyketide module of the polyketide synthase", Applicants believe that this phrase has support throughout the specification as filed. Examples of support for this phrase are discussed below.

Paragraph [0022] describes the generating of the second string. Specifically, it is described how "[t]his aspect of the invention is directed to the design and specification of PKS genes via the recombining of modules or portions of modules or sets of modules from *already known* and available PKS genes. In one mode, *all possible PKS genes encoding a desired polyketide from a set of genes in a database are generated*." (Emphasis added.)

Paragraph 37 states how "polyketides [are] synthesized by modular PKS genes [and] are built by the enzymatically controlled addition of primarily 2-carbon unit monomers … each polyketide may be represented as a string of 2-carbon unit [] monomers." Paragraph 39 shows an illustrative set of basic 2-carbon monomers. In addition, paragraph 28 describes how Figure 2 is "an illustrative set of 2-carbon unit monomers present in macrocyclic polyketides…."

Lastly, in order to further clarify the invention, the phrase "nor that [] each alphanumeric symbol also represents a polyketide molecule of a PKS gene" has been removed from claims 14, 18 and 19.

The Office also states that in claims 14, 18, and 19 that it "could not find adequate support therefore in the specification for such an alignment that consists of a combination of common alphanumeric symbols identified from the database such that the sequence of alphanumeric symbols in the alignment matches the first string, and wherein the alignment represents the structure of a new PKS gene capable of producing the desired polyketide."

Regarding the phrase "wherein the alignment consists of a combination of common alphanumeric symbols identified from the database such that the sequence of alphanumeric symbols in the alignment matches the first string, and wherein the alignment represents the structure of a PKS gene capable of producing the desired polyketide", Applicants believe that this phrase has support throughout the specification as filed. Examples of support for this phrase are discussed below.

Paragraphs [0049] to [0053] describe how a macrocyclic polyketide can be converted to a string of 2-carbon monomers by mapping the monomers onto the polyketide and how this can be performed manually or with computer assistance.

Then, paragraph [0055] and [0056] discusses how in one embodiment of the invention, a computer can be used to "align [a] library compound and target compound, … fill[] in the gaps using all possible combinations from all library members; … and output[] all these alignments." Paragraph [0057] states how the program "allows one to design and find PKS genes that encode PKS enzymes that are combinations of two or more different PKS enzymes."

In addition, paragraphs [0061] to [0063] describe how "[e]ach member of the coded PKS library can be selected as a STARTER unit." Then "[a]fter a STARTER is chosen, the TARGET is aligned with it." Paragraph [0062] discussed how "[w]ith the optimized alignment from the STARTER, other library entries are systematically used to complete the alignment, or fill in the gaps." Lastly, paragraph [0063] states how "[a]ssuming all modules in the TARGET are represented in the library, the ALIGNMENT is eventually completely filled."

Example 3 (paragraphs [0080] to [0086] "illustrates the alignment and design of novel PKS genes for the target epothilone", and Example 4 (paragraphs [0087] to [0094]) "illustrates the alignment and design of novel PKS genes for the erythromycin basic polyketide structure (6-dEB)."

Although Applicants believe that the inventions claimed in claims 14 and 19 find support in the specification as discussed above, in order to expedite prosecution and further clarify the inventions, Applicants have amended step (d) of claims 14 and 19 to read "generating ~~an alignment~~

a third string, wherein the ~~alignment consists of~~ third string comprises a combination of common alphanumeric symbols identified from ~~the database such that the sequence of alphanumeric symbols in the alignment matches the first string~~ step (c), and wherein the ~~alignment~~ third string represents the structure of a PKS gene capable of producing the desired polyketide." One of skill in the art at the time of the invention would understand that, for example, the "illustrative PKS" genes as described in Examples 3 and 4 *are* the "third string" as claimed in amended claims 14 and 19.

For the reasons set forth above, Applicants respectfully request that the rejection of claims 14-19 and 21-24 under 35 U.S.C. § 112, first paragraph, written description be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 300622005500. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: May 6, 2009

Respectfully submitted,

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